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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-------------------|
| 09/641,319 | 08/18/2000 | Michael R. Slater | PRMG-04578 | 7302 |
| 23535 | 7590 | 07/22/2005 | EXAMINER | |
| MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105 | | | | HUTSON, RICHARD G |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 1652 |

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/641,319 | SLATER ET AL. |
| | Examiner | Art Unit |
| | Richard G. Hutson | 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 April 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 22-30,40,44 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 22-30,40,44,48,50 and 51 is/are rejected.
- 7) Claim(s) 49 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicants amendment of claims 48 and 49 and the addition of new claims 50 and 51, in the paper of 4/27/2005, is acknowledged. Claims 22-30, 40, 44 and 48-51 are at issue and are present for examination.

Applicants' arguments filed on 4/27/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claim 49 is objected to because of the following informalities:

Claims 49 recites "...said mutation is a Asp to Ala...". This should be "...said mutation is an Asp to Ala...".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-30, 40 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office actions as it applied to previous claims 22-30, 40 and 44.

In response, applicants have amended claims 48 and 49, argue the rejection as it applies to the rejected claims.

Applicants again note in their traversal of claims 22-30, 40 and 44, that these claims "are copied from U.S. Pat. No. 5,939,301..." This is again acknowledged, as in the previous office action and with respect to U.S. Pat. No. 5,948,614. However, this statement remains confusing because it is unclear as to which claims or patents numbers applicants are in fact referring to.

Applicants continue to traverse this rejection for the reasons previously made of record and further direct the examiner to part (I) entitled "General Structural Features of DNA polymerases" on pages 33-37 of applicants' specification, which applicants submit in combination with the art demonstrates an understanding in the art regarding the various domains. Applicants continue to assert that this in addition to the specific examples provided in the specification warrant that the written description rejection be withdrawn.

Applicants' complete argument is acknowledged, however found non-persuasive for the reasons previously stated and those stated below.

Applicants are again reminded that the currently claimed genus remains large and variable with potentiality of comprising many different DNA polymerase type-I

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mutants many of which have not yet been identified. This genus encompasses any and all mutants of any pol-I type DNA polymerase or fragments thereof capable of DNA synthetic activity which is derived from *Thermotoga neapolitana*., including mutations occurring both within and outside of specifically defined domains.

While admittedly, applicants do teach examples of some specific non-naturally occurring Tne DNA polymerases, as well as the domains associated with the different enzymatic activities of Tne pol-I type DNA polymerase, this guidance remains insufficient to adequately describe the currently claimed genus which encompasses all compositions comprising any non-naturally occurring pol-I type DNA polymerases, or fragments thereof wherein said polymerase is derived from *Thermotoga neapolitana*. The claimed genus includes any Tne pol-I type DNA polymerase, fragment thereof, mutant or variant thereof.

In response to applicants submission that the examiner has not provided evidence to support applicants position that applicants have not adequately described the claimed genus, applicants submission is somewhat unclear as to what type of evidence applicants are referring to. It continues to be unclear as to what type of evidence would support what applicants have not described. To the contrary it is believed that applicants should provide evidence as to what **is** adequately described.

The claimed genus is infinitesimally large compared to that which applicants have shown possession of.

Given this lack of additional representative species as encompassed by the above claims, applicants have failed to sufficiently describe the claimed invention, in

such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 22 and 23 remain rejected under 35 U.S.C. 102(e) as being anticipated by Chatterjee et al. (U.S. Patent No: 5,912,155).

The rejection was stated in the previous office actions. In response to this rejection traverse the rejection as it applies to claims 22 and 23.

Applicants traversal of this rejection is based on applicants submission of a statement under CFR 1.608(b) with supporting declarations demonstrating that Applicant is *prima facie* entitled to a judgement relative to the patentee. The submission of the above declaration under CFR 1.608(b) with supporting declarations is not persuasive to overcome the present rejection at this time because as noted in the

MPEP, Section 2308, regarding filing of a declaration under 1.608 (b) "...the evaluation of a showing under 37 CFR 1.608(b) is made by an administrative patent judge".

However, an interference cannot be declared unless the common invention is patentable to the applicant. *Hilborn v. Dann*, 546 F.2d 401, 192 USPQ 132 (CCPA 1976). These claims are not patentable to the applicant because they fail to comply with the written description requirements of 35 USC 112.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22, 23, 25, 27-30, 44, 48, 50 and 51 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (U.S. Patent No: 5,912,155) as applied to claims 22, and 23 above, and further in view of Erlich et al.(Science 252:1643-1651, June 1991).

The rejection was stated in the previous office action as it applied to claims 22-30, 40, 44 and 48. In response to this rejection applicants have amended claims 22 and 23 and traverse the rejection as it applies to the newly amended claims. Newly added claim 50 and 51 are included in the rejection for the reasons previously stated for claims 22-30, 40, 44 and 48.

Applicants traverse this rejection in combination with the above 102 rejection on the basis that applicants have provided the proper documentation to remove Chatterjee et al. as an art reference and place the application in an interference with the '301 patent.

Applicants comments are acknowledged, however, the rejection is maintained until the time at which all claims are otherwise determined to be allowable, in which case the application will appropriately be placed into interference.

Conclusion

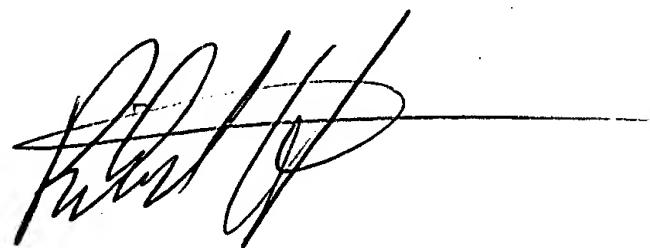
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
10/20/2004